The NuvaRing® is a flexible, transparent, colorless vaginal ring containing a combination of etonogestrel and ethinyl estradiol. The NuvaRing® is placed anywhere in the vagina for 3 weeks of continuous use. It is then removed for a one-week break during which withdrawal bleeding occurs. A new ring is inserted one week after the last ring was removed. It is 98.8% effective in preventing pregnancy if used correctly.

## I. Client Selection

- A. Indications NuvaRing® may be provided:
  - When contraindications do not exist;
  - 2. Post-Pregnancy:
    - a. Immediately after abortion
    - b. May initiate 3 4 weeks after second trimester abortion or postpartum and nonlactating.
    - c. Should exercise caution in nursing women less than six months postpartum.

      Document discussion of potential risks/benefits such as decrease in milk supply.
- B. Contraindications refrain from providing (Based on WHO Medical Eligibility Criteria)
  - 1. History of idiopathic or postpartum deep vein thrombosis or thromboembolism; known thrombogenic mutations such as Protein C or S resistance and Factor V Leiden (WHO Medical Eligibility Criteria, 2004) or EXTENSIVE familial history of deep vein thrombosis. (Thrombosis related to either a known trauma or an IV needle is not necessarily a reason to avoid use of NuvaRing®.);
  - 2. History of thrombotic cerebrovascular accident (stroke);
  - 3. Vascular, coronary artery, ischemic heart disease, myocardial infarction or current angina pectoris, or history thereof;
  - 4. Age >35 years old and smoking >15 cigarettes per day;
  - 5. Hypertension: systolic ≥160 or diastolic ≥100;
  - 6. Diabetes mellitus with clinically manifested vascular disease (diabetic nephropathy, retinopathy, neuropathy or peripheral vascular disease);
  - 7. Known or suspected carcinoma of the breast or endometrium, or other estrogen dependent neoplasia; NuvaRing® use may be considered, in consultation with the physician, for women with a past history of breast cancer but no evidence of estrogen dependence in the cancer and no recurrence for 5 years.
  - 8. Benign hepatic adenoma, liver cancer, or history thereof; active viral hepatitis, severe cirrhosis or markedly impaired liver function currently;
  - 9. Migraine headaches with focal neurological symptoms (visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities);
  - 10. Unexplained abnormal vaginal or uterine bleeding, NOT including irregular menses;

- 11. Planned major surgery with prolonged immobilization or any surgery on the legs;
- 12. Suspected pregnancy;
- 13. Lactation (<6 weeks postpartum).
- 14. Hypersensitivity to any of the components of NuvaRing®;
- C. Special Conditions Requiring Further Evaluation: The theoretical/proven risks generally outweigh the advantages of using the method. The patient must be provided with information regarding the way in which these conditions may add to a health risk for her. This discussion must be documented. (Based on WHO Medical Eligibility Criteria)
  - 1. Adverse cardiovascular risk profile (see V. Management of Women with Special Conditions Requiring Further Evaluation p. 4, this protocol);
  - 2. Active or medically treated gallbladder disease, history of COC-related cholestasis.
  - 3. Migraine headaches without focal neurological symptoms (visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities) [see V. Management of Women with Special Conditions Requiring Further Evaluation p. 6, this protocol];
  - 4. Elevated blood pressure measurements 140-159/90-99 on three separate visits within a two week period. (See Flow Chart for Management of Clients Using NuvaRing® Who Develop High Blood Pressure page 6 of this protocol);
  - 5. Age  $\geq$ 35 years old and smoking <15 cigarettes per day;
  - 6. Seizure disorder, currently taking anticonvulsants that affect liver enzymes (see V. Management of Women with Special Conditions Requiring Further Evaluation p. 7, this protocol);

#### II. Patient Education/Informed Consent - Must Include:

- A. All clients choosing to use NuvaRing® must receive the following information:
  - 1. Fact sheet on all contraceptive options available, if she is a new client or is undecided as to what method she wishes to use:
  - 2. A copy of the FDA approved detailed patient labeling pamphlet. The importance of reading the FDA pamphlet must be explained to the client.
  - 3. Instructions on when to insert and remove NuvaRing®. (For instructions, see Contraceptive Technology, Eighteenth Edition, pp. 448)
  - 4. Information that the effectiveness of NuvaRing® may be decreased by some medications (See V. Drug Interactions p. 7, this protocol)
  - 5. The importance of scheduled follow-up visits (See Follow Up, VII, page 7 of this protocol)
  - 6. Importance of informing their other providers of their use of NuvaRing®
  - 7. Information regarding discontinuation of the Nuvaring®, and the recommendation that

- she complete the cycle she is taking. If she does not wish to become pregnant, she should start using another method before the day she was due to insert another ring.
- 8. Information regarding sexually transmitted infections, including counseling that NuvaRing® provides no protection. Use of either male or female condoms should be recommended for clients in need of protection from STDs.
- B. All clients choosing to use NuvaRing® must sign the following:
  - 1. General family planning program consent
  - 2. Hormonal contraceptive consent for the provision of Nuvaring® (does not need to be reinitialed every year unless there is a change in health status)

## III. Medical Screening And Evaluation

- A. History as per Title X Guidelines (See Nursing Policy Section IV Health Care Services).
- B. Examination as per Title X Guidelines (See Nursing Policy Section IV Health Care Services).
- C. Laboratory tests per Title X Guidelines (See Nursing Policy Section IV Health Care Services).
- D. Provision of NuvaRing® through Delayed Exam See Delayed Exam protocol

# IV. Provision of NuvaRing®

CURRENT METHOD	INSERT RING	BACK UP
No effective contraception in preceding cycle	On or prior to day 5 of cycle, OR during this office visit if pregnancy can be ruled out (Quick Start), OR the day after taking emergency contraceptive pills (ECPs) (Jump Start)	Back up method recommended for 7 days
COC's or Ortho Evra® in preceding cycle	Anytime within 7 days of the last COC tablet taken or Evra® patch removed (no later than when a new cycle would have been started)	None
Progestin-only pills (POPs) in preceding cycle	Any day of the month. There should be no skipped days between last pill and first day of Nuvaring® use	Back up method recommended for 7 days
Implanon® implant in preceding cycle	On the same day the implant is removed	Back up method recommended for 7 days
DMPA in preceding cycle	On or before the day when the next injection is due	Back up method recommended for 7 days
ParaGard® or Mirena® in place	On the same day that the IUD is removed	Back up method recommended for 7 days
Post first trimester abortion	Within 5 days of a completed procedure	None

CURRENT METHOD	INSERT RING	BACK UP
Post second trimester abortion and postpartum	3-4 weeks post second trimester abortion; 3-4 weeks postpartum in women who elect not to breast feed, if menses has not restarted; >6 months in lactating women.	Back up method should be considered for 7 days
Any other contraceptive method	On first day of cycle On days 2-5 of cycle	No back up method is needed  Back up method should be
	On days 2-5 of cycle	Back up method should be used for 7 days

## V. Management Of Women With Special Conditions Requiring Further Evaluation

A. Adverse Cardiovascular Risk Profile

If a woman has two or more risk factors, the case must be evaluated by, and use of NuvaRing® approved by a physician:

- 1. Age  $\geq$ 35;
- 2. Smoking cigarettes;
- 3. High cholesterol levels;
- 4. Diabetes:
- 5. Chronic hypertension.

## B. Diabetes mellitus

- 1. NuvaRing® use in women with diabetes must be individualized. As risk factors increase in number or severity, it may become less appropriate to prescribe NuvaRing®.
- 2. Consider involving the primary care provider managing the client's diabetes if she is initiated on NuvaRing®.

## C. High Blood Pressure

- 1. If hypertension is controlled with diet or medication, the complete cardiovascular risk profile (A.1 5 above) must be considered.
- 2. NuvaRing® may induce hypertension in a very small percentage of previously normotensive women. If a NuvaRing® user is found to have a significant rise in blood pressure to 140 systolic or above/ 90 diastolic or above, the rise could be due to the NuvaRing®.
- 3. Management Please refer to the flow chart on the next page for management of hypertension that occurs in women using NuvaRing®:

# Flow Chart for the Management of Clients Using NuvaRing® Who Develop High Blood Pressure

SYSTOLIC 140 or above And/or DIASTOLIC 90 or above

Have client return two or more times within two weeks in a resting state for reevaluation.

If any two or more readings on at least two different visits are  $\geq$ 140 systolic or >90 diastolic, consider the following options:

- +Physician consultation
- +Refer for medical evaluation
- +Switch to another method (progestin-only is OK)

Diastolic of ≥100 on any one occasion – stop NuvaRing® immediately. **Initiate interim method of contraception**; client must be referred for a medical evaluation.

Continuation of NuvaRing® requires documentation of physician approval and a plan for follow-up.

If NuvaRing® is discontinued, re-check BP within three months.

- If still ≥140 systolic or ≥90 diastolic, refer for evaluation.
- If < 140 systolic or <90 diastolic, may then try a very low dose (20 ug estrogen) combination pill or progestin-only method.

If very low dose (20 ug estrogen) combination pill or progestin only method is initiated:

- Monitor BP monthly for three months. If BP rises to ≥140 systolic or ≥90 diastolic at any time, discontinue estrogen-containing hormonal contraceptives.
- Offer alternative method.
- Recheck BP within 3 months. See first bullet in this box.

## D. Headaches

- 1. Management of headaches that start or worsen after the initiation of NuvaRing® is up to the discretion of the practitioner and client and may include any of the following:
  - a. Referral for headache evaluation:
  - Change in birth control method, including very low dose COCs (20 ug) or progestin only methods;
  - c. For headaches during the hormone free interval, discuss with the client the off-label use of leaving the NuvaRing® in for one calendar month (per ring) with no ring-free period. (Refer to bottom of page 7 of this protocol.)
- 2. Common Migraine Headaches (without focal neurologic symptoms [visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities])
  - a. A trial of NuvaRing® may be provided for women with a history of migraine headaches <u>without</u> focal neurological symptoms. The client must be advised to report any increase in the frequency and severity of such headaches.
  - b. If migraines worsen in frequency or severity, or if focal neurological symptoms or signs occur (visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities), NuvaRing® must be discontinued. Women who develop focal neurological symptoms or signs should be referred promptly for neurologic evaluation.

#### E. Seizure disorders

- 1. A large majority of women with seizure disorders will notice no change in the frequency or severity of seizure activity as a result of initiating the NuvaRing®.
- 2. Concurrent use of antiseizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in NuvaRing® users. It is the responsibility of the provider to review a client's anti-seizure medication(s) for potential drug interaction with NuvaRing®.
- 3. Use of backup barrier methods, and the benefits and risks of using NuvaRing® in women with seizure disorders should be discussed with women who use antiseizure drugs but who need a high degree of protection. Women who are on certain antiseizure medications and choose to use NuvaRing® should be advised to use a back up method, such as condoms, for 3 months. Any breakthrough bleeding during this time may indicate a decrease in circulating levels of estrogen and progestin. Such a decrease could result in ovulation. Continued use of a barrier method with the NuvaRing® (dual method use) or switching to Depo Provera, Implanon, or an IUD may be advised.

## F. Drug Interactions

- 1. Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in NuvaRing® users. (See V. E. on previous page)
- 2. Gabapentin (Neurontin), vigabatrin, ethosuximide and lamotrigine (Lamictal) have no effect on this enzyme system and do not interfere with contraceptive effectiveness.

- Valproate/ Valproic Acid (Depakote) and felbamate (Felbatol) do not increase breakdown of hormones and may even increase hormone levels.
- 3. Rifampin increases hepatic clearance of estrogens and progestins; it is recommended that clinicians not prescribe NuvaRing® for women on this drug (Contraceptive Technology, Eighteenth Edition, p. 419).
- 4. Antibiotics: Although women on antibiotics do have lower serum progestin and estrogen levels, the levels remain well within the therapeutic range for sex steroids. Back up methods should not be necessary. (Contraceptive Technology, Eighteenth Edition, p. 419)
- 5. NuvaRing® can decrease clearance of benzodiazepines such as diazepine (Valium), nitrazepine, chlordiazepine, alprazolam, which suggests the need for lower doses of these medications. Clearance of bronchodilators such as theophylline, aminophylline and caffeine as well as anti-inflammatory corticosteroids may also be reduced.
- 6. More rapid clearance of acetaminophen and aspirin is also reported.
- 7. The FDA has alerted providers that the use of St. John's Wort may decrease the therapeutic effect of NuvaRing®.

# VI. Guidelines For Ring Use And Management Of Problems/Side Effects

- A. The NuvaRing® must be stored in a refrigerator at 36-46 degrees F° prior to dispensing. The NuvaRing® may be stored by the client for up to 4 months at or below 77 degrees F° (room temperature). The patient label should have an expiration date that does not exceed 4 months from the date of dispensing or the product expiration date, whichever comes first.
- B. The exact position of NuvaRing® in the vagina is not important for it to work.
- C. If the patient feels discomfort, NuvaRing® is probably not inserted back far enough in the vagina. The patient should use her finger to gently push NuvaRing® further into her vagina.
- D. The NuvaRing® should be inserted and removed on the same day of the week (three weeks apart) and at about the same time.
- E. Place used ring in the foil pouch it came in and dispose of it in a waste receptacle. Do not throw it in the toilet.
- F. The menstrual period will usually begin two to three days after the ring is removed and may not have finished before the next ring is inserted.
- G. If NuvaRing® slips out of the vagina:
  - 1. Rinse NuvaRing® with cool to lukewarm (not hot) water and reinsert as soon as possible.
  - 2. If the patient completely lost NuvaRing®, a new one is inserted and she continues on the same schedule she would have used before the ring was lost.
  - 3. If the ring has been out of the vagina for more than 3 hours a back up method is recommended for 7 days.

- H. If NuvaRing® is in the vagina for too long
  - 1. Ring is left in for an extra week or less: Remove ring and insert a new ring after a one-week ring-free break;
  - 2. Ring is left in the vagina for more than 4 weeks: Remove ring, rule out pregnancy, insert new ring;
  - 3. Back up method recommended for 7 days.
- I. Missed period

Rule out pregnancy if:

- 1. NuvaRing® was out of the vagina for more than 3 hours during the three weeks of ring use.
- 2. There was a delay of longer than one week in inserting new ring
- 3. There were two missed periods in a row
- 4. NuvaRing® was in place more than 4 weeks
- J. Extended Use or Continuous Cycling: Consider offering clients the opportunity of fewer withdrawal bleeds during the year by skipping the ring-free week, particularly if they experience estrogen withdrawal symptoms such as headache during the ring-free week. Each ring can be left in place for one calendar month, then removed and immediately replaced with a new ring on the first of each month. The prescription is still written for 12 rings/year.

## VII. Follow Up

- A. The new combined hormonal contraceptive user must be reassessed within 3 months after beginning NuvaRing® and at least annually thereafter.
- B. Please refer to Section V (Health Care Services) in the Nursing Policy Manual for a complete review of the requirements for revisits for NuvaRing® users.
- C. At each NuvaRing® related medical visit, the patient should be asked about changes in personal history, possible side effects, and her menstrual cycle/bleeding pattern.

The following is a sample of a Hormonal Consent Form. This form can be downloaded from the Women's Health Unit website at:

http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

HORMONAL CONSENT						
ORAL CONTRACEPTIVE (Combined and POP) • ORTHO EVRA • NUVARING						
I have been given information about and have had a chance to ask questions about:						
☐ Ɓirth control pills: ☐ Combined ☐ Ɗrtho Evra patch ☐ ƁuvaRing						
Progesterone Only  I know that:						
<ul> <li>Birth control pills and Ortho Evra patch do not require a back up method if I start on the first day of my period.</li> </ul>						
<ul> <li>Progesterone only pills (POP) only have the hormone progesterone. This may make the effectiveness slightly lower than combined birth control pills. I know that I need to take a pill every day without a break. There is no hormone-free week like there is with combined pills. My periods might be irregular.</li> </ul>						
<ul> <li>NuvaRing is left in the vagina for three weeks from the day I insert it, and is then removed and thrown away. A new ring is inserted one week (7 days) after removal of the old one.</li> </ul>						
<ul> <li>Ortho Evra (the patch) results in a 60% increase in exposure to estrogen compared to the average birth control pill. It is not known whether this results in a significant increased risk of blood clots.</li> </ul>						
<ul> <li>The hormonal methods listed above do not provide me with protection from sexually transmitted diseases. If I need this protection, I have been advised to use condoms PLUS this method.</li> </ul>						
I have been told that there may be some medical risks when using any of the combined hormonal methods that could include such things as stroke, blood clots, or liver tumors. I have been given a copy of the "Detailed Patient Labeling" which tells how often these problems happen.						
I understand that the cardiovascular risks of this method may get worse with age, especially over 35 years of age, and with smoking. I know that the serious health problems that this method can cause are rare. I know to call the clinic or my private doctor, or to go to the emergency room if I have any of these danger signs:						
<ul> <li>Severe abdominal pain;</li> <li>Chest pain;</li> </ul>						
Severe headaches;						
Changes in my vision;						
Severe leg pain.						
If I wish to discontinue my method, I have been advised that it is better for me to finish the cycle I am taking before stopping the method. If I do not wish to become pregnant, I must start on another method immediately.						
Patient signature Date						
Staff signature Date						
Interpreter's Statement						
I have translated the information and advice presented orally to the client who has chosen:						
☐ Combined birth control pills ☐ Progesterone only birth control pills						
☐ Ortho Evra Patch ☐ NuvaRing						
I have also read the consent form to her in a language she understands and explained its contents to her. To the best of my knowledge and belief, she understands this explanation and voluntarily consents to the use of the method marked above.						
Interpreter's signature Date						

The following is a sample of a Hormonal Evaluation Form. This form can be downloaded from the Women's Health Unit website at:

http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

Name	Today's date		
Date of birth	Age		
First day of last period			
1. Please check your current met	hod:		
<ul><li>☐ Birth control pill (Combined)</li><li>☐ Evra</li><li>☐ Implanon</li></ul>	☐ Birth control pill (Progesterone only)☐ Nuvaring		
2. Are you having any problems v			
3. Do you have any questions?  Explain:			
4. Have you had any health probl □No □?Yes Explain:	ems or seen a physician since your last visit?		
5. Are you taking any other medic			
6 Check if you have had any of t	he following since you started your method:		
or oncor in you have had any or t			
Severe headaches	☐ Severe abdominal pain		
☐ Severe headaches ☐ Dizziness	<ul><li>☐ Severe abdominal pain</li><li>☐ Depression</li></ul>		
☐ Severe headaches ☐ Dizziness ☐ Vision changes	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li></ul>		
☐ Severe headaches ☐ Dizziness ☐ Vision changes ☐ Chest pain	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li><li>□ Heavy bleeding</li></ul>		
☐ Severe headaches ☐ Dizziness ☐ Vision changes	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li></ul>		
☐ Severe headaches ☐ Dizziness ☐ Vision changes ☐ Chest pain	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li><li>□ Heavy bleeding</li></ul>		
Severe headaches Dizziness Vision changes Chest pain Severe leg pain	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li><li>□ Heavy bleeding</li></ul>		
Severe headaches Dizziness Vision changes Chest pain Severe leg pain Client Signature	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li><li>□ Heavy bleeding</li><li>□ Weight gain</li></ul>		
Severe headaches Dizziness Vision changes Chest pain Severe leg pain  Client Signature  TO BE COMPLETED BY STAFF	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li><li>□ Heavy bleeding</li><li>□ Weight gain</li></ul>		
Severe headaches Dizziness Vision changes Chest pain Severe leg pain  Client Signature  TO BE COMPLETED BY STAFF	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li><li>□ Heavy bleeding</li><li>□ Weight gain</li></ul>		
Severe headaches Dizziness Vision changes Chest pain Severe leg pain Client Signature	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li><li>□ Heavy bleeding</li><li>□ Weight gain</li></ul>		
Severe headaches Dizziness Vision changes Chest pain Severe leg pain  Client Signature  TO BE COMPLETED BY STAFF S:	<ul><li>□ Depression</li><li>□ Nausea or vomiting</li><li>□ Heavy bleeding</li><li>□ Weight gain</li></ul>		

The following is a sample of a Headache Evaluation Form. This form can be downloaded from the Women's Health Unit website at:

http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

			Age		
When you have headaches, how often do you (Circle one answer per question)					
ning on before they become headaches?	Never	Rarely	Usually	Always	
e to severe pain?	Never	Rarely	Usually	Always	
g, pounding, or throbbing pain?					
ain on one side of your head?					
ain when you move, bend over or walk stai	rs? Never	Rarely	Usually	Always	
	Never	Rarely	Usually	Always	
g?					
by light?					
es, spots, or light flashes?	Never	Rarely	Usually	Always	
thcare provider more complete informa	ion, please answer	these a	dditiona		
lists for illument have also suffer for much and	h 2		V	NI.	
have you had at least 5 hard school with the	acnes!	ab arra2		No No	
	le symptoms noted				
ic(s) do you take for your neadaches:					
tatements that are true:					
medicine does not make me pain free.					
nedicine does not treat other symptoms (e.	g., nausea, sensitivit	y to ligh	nt).		
	veek.				
medicine makes me drowsy.					
nay last 4 to 72 hours (untreated or unsucce	essfully treated).				
following that ever bring on one of these	headaches:				
smells, or sounds	Too little slee	ep or too	much sl	eep	
nus pain/pressure	Lack of caffeine or too much caffeine			caffeine	
on	Changes in mood/excitement				
trual cycle/hormonal changes	Foods or alco	holic b	everages		
	g, pounding, or throbbing pain? ain on one side of your head? ain when you move, bend over or walk stair g? by light? by sound? or avoid daily activities? own in a quiet, dark room? es, spots, or light flashes?  thcare provider more complete informat iate family members also suffer from head; e, have you had at least 5 headaches with th d you first experience these headaches? ow often do you get these headaches? tatements that are true: medicine does not make me pain free. medicine does not treat other symptoms (e.g. ache medicine more than 2 or 3 times per your one kind of medicine for my headaches. may last 4 to 72 hours (untreated or unsucces following that ever bring on one of these smells, or sounds	g, pounding, or throbbing pain?  ain on one side of your head?  ain when you move, bend over or walk stairs?  Never Never  Never  Never  Never  Never  by light?  by sound?  or avoid daily activities?  own in a quiet, dark room?  es, spots, or light flashes?  Never  thcare provider more complete information, please answer  iate family members also suffer from headaches?  e, have you had at least 5 headaches with the symptoms noted a dyou first experience these headaches?  ow often do you get these headaches?  ow often do you get these headaches?  tatements that are true:  medicine does not make me pain free. medicine does not treat other symptoms (e.g., nausea, sensitivit ache medicine more than 2 or 3 times per week. medicine makes me drowsy.  on one kind of medicine for my headaches. may last 4 to 72 hours (untreated or unsuccessfully treated).  following that ever bring on one of these headaches:  smells, or sounds  ——Too little sleet  ——Missed meals  ——Too little sleet  ——Missed meals	g, pounding, or throbbing pain?  ain on one side of your head?  ain when you move, bend over or walk stairs?  Never Rarely	g, pounding, or throbbing pain?  ain on one side of your head?  ain when you move, bend over or walk stairs?  Never Rarely Usually Never Rarely Usually Never Rarely Usually Never Rarely Usually Usually Never Rarely Usually Usually Never Rarely Usually Usually Never Rarely Usually Usually Never Rarely Usually Usually thcare provider more complete information, please answer these additionatiate family members also suffer from headaches?  Let head of the separate of the separ	